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10/628,050	07/28/2003	Jacques Louis Poret	Rev 00-25	4070

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,050

Applicant(s)

PORET, JACQUES LOUIS

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-29 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-29 and 31-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Amendments and Remarks received on October 21, 2004 is acknowledged. Claims **21-29 and 31-41** are pending in this application. Claims 1-20 and 30 stand cancelled.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments of 10/21/04. However, the argument based on the preamble will be addressed since applicant has repeatedly argued this point.

The applicant argues that the references do not teach a make-up foundation.

In response to applicant's arguments, the recitation "make-up foundation" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In instant case, the preamble does not provide a structural limitation; rather it functions to provide the intended use of the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-22, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greff (WO 98/06695) in view of Deckner (4,563,346).

Greff discloses a topical composition containing instant melatonin derivative, palmitoyl-methoxytryptamine for the treatment of the skin. See Figure (a). The dermatopharmaceutical is utilized for hydrating, regenerating, its anti-seborrheic properties, and bleaching the skin. See abstract. The reference discloses the instant derivatives allow the compound to be easily incorporated into a cosmetic product and has a stronger affinity for the epidermis. Moreover it is not irritating to the skin, and is stable and effective. (Note pg. 2, last paragraph and pg. 3, first paragraph). Greff teaches the compound may be formulated in the amount of 0.0001-10% into an o/w or w/o emulsions, milks, gels, lotions, sticks, crayons, etc. See page 5. The dermatopharmaceutical (the melatonin derivative) may be used as an anti-wrinkle/anti-agent formulation, for moisturizing, and protecting cream against the effects of UV radiation. See page 5. Greff teaches the melatonin derivatives may be combined with any ingredient commonly used in cosmetics. For instance, example 2 teaches a face cream containing 1.5% instant melatonin derivative, 2.4% Brij 721 (steareth-21), 2.6% Brij 72 (steareth-2), 8% Arlamol, 0.5% beeswax, 3% Abil (stereoxy dimethicone), 3% propylene glycol (humectant), 0.25 carbopol, 0.25

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triethanolamine, and water to balance. The composition described in example 2 provides a better appearance to the skin, i.e. the skin is more hydrated, less wrinkled, clearer, and firmer. Talc and other mineral supports are taught in claim 5. Note talc reads on "at least one pigment".

Greff does not teach the use of the instant linear volatile silicone oil and silicone emulsifier.

Deckner teaches a topical delivery system comprising a volatile silicone oil (hexamethyldisiloxane and decamethylcyclopentasiloxane) and silicone emulsifier (dimethicone copolyol) and skin treatment composition to deliver an active ingredient. The composition contains co-emulsifiers such as non-ionic emulsifiers taught on column 3, line 63 to column 4, lines 5. Deckner teaches an ideal topical delivery system is stable as possible and delivers the therapeutic ingredient in a manner that it adheres to the skin for a long period of time while the other non-therapeutic evaporate from the skin. See column 1, lines 15-60. Deckner teaches the traditionally oil/water emulsions are perceived as oily or greasy which do not spread well onto the skin. Deckner teaches the inventive formulation provides for an emulsion system that has a unique non-greasy feel, which has a rich feel on application, dries quickly, spreads easily, and leaves skin silky. See column 2, lines 25-31. Further, the delivery system provides a long lasting film, which is resistant to sweat. Thus, Deckner teaches the use of the delivery system for sunscreen formulation since it cannot be removed by perspiration and swimming and for moisturizing compositions since it provides a substantive moisturizing film that produces long-lasting moisturizing properties. See column 4. The delivery system has 5-40% of the silicone oil and water in the amount of 40-85%. See column 3, lines 55-62.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Greff and Deckner and utilize a linear volatile silicone oil. One would have been motivated to do so since Deckner teaches a delivery system containing the instant linear volatile silicone oil and silicone emulsifier for therapeutic agents that has a unique non-greasy feel, which has a rich feel on application, dries quickly, spreads easily, and leaves skin silky. Further, Deckner teaches the silicone delivery system provides a long lasting film so that the active agent can adhere to the skin to provide a lasting benefit. Moreover, one would reasonably expect success from the combination since Greff teaches palmitoyl-methoxytryptamine for topical delivery for moisturizing the skin and Deckner teaches the instant silicone oil provides an excellent vehicle to moisturize the skin.

Claims 23, 27-29, 31-38, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greff (WO 98/06695) in view of Deckner (4,563,346) in further view of Cohen et al (5,560,917).

As set forth above, Greff discloses a topical composition containing instant melatonin derivative, palmitoyl-methoxytryptamine for the treatment of the skin. See Figure (a). The dermatopharmaceutical is utilized for hydrating, regenerating, and bleaching the skin. See abstract. The dermatopharmaceutical may be used as an anti-wrinkle/anti-agent formulation, for moisturizing, and protecting cream against the effects of UV radiation. See page 5. Talc and other mineral supports are taught in claim 5.

Deckner teaches a topical delivery system comprising a volatile silicone oil (hexamethyldisiloxane) and silicone emulsifier (dimethicone copolyol) and skin treatment composition to deliver an active ingredient.

The references do not teach the amount of pigments in the composition.

Cohen et al teach a water-in-oil emulsion cosmetic composition to protect the skin from the environment, improves complexion, etc. See abstract. The composition retards effects of aging caused by exposure of the skin to sunlight and natural aging by moisturizing. Further, the composition provides one single easy application of a composition that provides an attractive coloration to the skin while providing bioactive agents, moisturizing agents, and sunscreen. See column 2, lines 40-55. Cohen et al teach the sunscreens such as titanium dioxide and zinc oxide in the amount of 0.1-20%. See column 4, lines 10-25 and Table 1. The concentration depends on the desired effect and blocking ability of the sunscreen. See column 5, lines 4-20. Cohen also teaches the use of pigments/colorants such as titanium dioxide, *talc*, red iron oxide, etc. in the amount of 0.5-20% depending on the color desired. Cohen teaches the use of volatile silicone oils, such as cyclomethicone, as the carrier oil in the oil phase. See examples. Lastly, Cohen teaches the use of natural oils as hydrating agents.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Greff, Deckner, and Cohen et al and utilize the instant amount of pigment. One would have been motivated to do so firstly since Cohen et al teach the use of 0.5-20% pigments such as talc as pigments that provide color to the composition and the amount depends on the desired color. Moreover, one would reasonably expect success by the instant combination since Greff teaches the use of talc in the composition. Therefore, it is prima facie obvious to manipulate the concentration of the talc found in Greff depending on the desired color, as taught by Cohen et al.

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Secondly, one would have been motivated to utilize another pigment such as titanium dioxide in the instant amount, to provide sun-screening benefits since Cohen teaches the use of pigments to filter UV light. Moreover, one would reasonably expect success by the instant combination since Greff teaches the use of mineral supports in the composition and Greff teaches the a composition to filter UV light. Therefore, one would have been motivated to utilize the instant amount of pigment to further provide a sunscreen benefit in the Greff's protecting cream against UV radiation (see page 5).

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greff (WO 98/06695) in view of Deckner (4,563,346) in view of Cohen et al (5,560,917) in further view of JP 408283144 (abstract only).

As set forth above, Greff teaches the instant compound in a face cream, sunscreen, etc. Deckner teaches the use of the instant linear silicone oil as a delivery system for topical compositions. Cohen et al teach the amount of pigment contained in a cosmetic composition.

The references do not teach the use of salicylic acid in the formulation.

JP teaches the use of salicylic acid on the amount of 0.01-2% with titanium oxide in a w/o or o/w emulsions to depigment the skin. The salicylic acid has the ability of inhibiting melanin synthesis. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and incorporate salicylic acid in the formulation. One would have been motivated to do so since JP teaches the use of salicylic acid to depigment the skin. Therefore, one would expect an additive effect if not a synergistic effect utilizing the combination of two depigmenting agents.

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Claims 21-29 and 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al (5932608) in view of Greff (WO 98/06695), in further view of Sang et al (6,143,310).

Nguyen et al disclose a topical composition containing a melatonin derivative (6-Hydroxymelatonin) for whitening and depigmenting the skin. The cosmetic or dermatological composition contains conventional additives known to those skilled in the art, such as emulsifiers, gelling agents, active agents, antioxidants, screening agents, dyes, etc. See column 4, lines 13-26. Exemplary oils utilized are plant oils, mineral oils, and silicone oils such as cyclomethicone. Exemplary hydrophilic active agents are glycerol, sorbitol, and allantoin. Exemplary UV screening agents are titanium oxide and zinc oxide in the amount of 0.01-20%. See column 4, lines 44-65. The dermocosmetic may be formulated into w/o or o/w emulsions in cream form wherein emulsifiers are utilized in the range of 0.1-15% and co-emulsifiers in the amount of 0.05-10%. Lastly, the composition may take the form of a protective cream for the face or body, treatment lotion, foundations, or tinted creams. For foundations and cream, the composition contains a pigment. See column 5, lines 1-5. The examples teach an oil in water emulsions wherein the composition contains 0.05% of 6-Hydroxymelatonin, 5% octyldodecanol, 11% sunflower oil, 5% cyclomethicone, 4% glycerol, 0.6% glyceryl stearate, 0.6% PEG-100 stearate, 1.2% PEG-20 stearate, and water to balance.

Nguyen et al do not teach instant melatonin derivative, palmitoyl-methoxytryptamine. Further, although Nguyen teaches a cyclic volatile silicone oil, Nguyen does not specify the use of a linear volatile silicone oil.

Greff discloses a topical composition containing instant melatonin derivative, palmitoyl-methoxytryptamine for the treatment of the skin. See Figure (a). The dermatopharmaceutical is utilized for hydrating, regenerating, and bleaching the skin. See abstract. The reference discloses the instant derivatives allow the compound to be easily incorporated into a cosmetic product and has a stronger affinity for the epidermis. Moreover they are not irritating to the skin, they are stable and effective. (Note pg. 2, last paragraph and pg. 3, first paragraph). Greff teaches the compound may be formulated in the amount of 0.0001-10% into an o/w or w/o emulsions, milks, lotions, sticks, crayons, etc. See page 5. The dermatopharmaceutical may be used as an anti-wrinkle/anti-agent formulation, for moisturizing, and protecting cream. See page 5. Example 2 teaches a face cream containing emulsifiers, propylene glycol, oil, and water in the instant amount. See example 2. Talc and other mineral supports are taught in claim 5.

Sang et al teach a cosmetic composition to containing salicylic acid to regulate oily skin. See abstract. Sang teaches the use of salicylic acid to regulate the skin, reduce oily appearance, and provide a uniform complexion. See column 3, lines 45-60. The composition is the form of an emulsions wherein the oil phase contains silicone oil, non-silicone oils, or mixtures thereof. The preferred embodiment contains a mixture of volatile silicone and non-silicone oils in the amount of 1-50. See column 3, lines 60-65. The use of silicone oils provide for skin conditioning properties. Suitable volatile silicone oils include cyclic oils such as cyclomethicone and linear oils include hexamethylsiloxane (Dow 200). The cyclic silicone oils have a viscosity of less than 10 centistokes and linear oils have a viscosity less than 5 centistokes. See column 4. Further Snag teaches the use of instant silicone surfactants (DC 3225c) in composition and the instant amount of the surfactant is taught in the examples.

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Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Nguyen et al and Greff and substitute the instant melatonin derivative in place of Nguyen's melatonin derivative in the depigmenting composition. One would have been motivated to do so since Greff teaches the instant compound has certain advantages such as stronger affinity for the epidermis, stability, and effectiveness compared to other melatonin derivatives. Further motivation to do so being that a homogenous product is yielded since Greff teaches the ability of the instant compound to easily incorporate into a cosmetic carrier.

Secondly, it would have been further obvious for one of ordinary skill in the art at the time the invention was made to further look to Sang et al and utilize the instant linear volatile silicone oil in place of Nguyen's cyclic volatile silicone oil. One would have been motivated to do so since Sang et al teach the functional equivalence of both cyclic and linear volatile silicone oils in their ability to provide skin conditioning. However, Sang also teaches linear volatile silicone oils have a lower viscosity compared to the cyclic volatile silicone oils. Thus, one would have been motivated to substitute Nguyen's cyclic silicone oil with the instant linear silicone oil, if one wanted desired to formulate a composition with a lower viscosity. Therefore, it is prima facie obvious to utilize either cyclic or linear silicone oils (volatile) depending on the desired viscosity of the composition. Furthermore, one would have been motivated to add Sang's salicylic acid to Nguyen's composition since Sang teaches the use of salicylic acid provides a uniform complexion. Therefore, a skilled artisan would expect an additive effect by the combination of both active agents since Nguyen teaches the a depigmenting composition to provide even complexion and Sang teaches salicylic acid helps to provide a uniform complexion.

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Conclusion

None of the claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG


MICHAEL G. HARTLEY
PRIMARY EXAMINER